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DSMALLS SALE #00000002 Mailroom Dt: 12/31/2007 230785 10815320
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01729/2008 DSMALLS 00000002 230785 10815320
01 FC:1251 120.00 CR

1251

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: H. Binz et al.	)	
	)	
Title: CARRIER PROTEIN HAVING AN ADJUVANT EFFECT, IMMUNOGENIC COMPLEX CONTAINING IT, PROCESS FOR THEIR PREPARATION, NUCLEOTIDE SEQUENCE AND VACCINE	)	
	)	
Serial No. 10/815,320	)	Group Art Unit: 1645
	)	
Filed: April 1, 2004	)	Examiner: S. Devi

REFUND REQUEST LETTER

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

As per the attached Notice from the USPTO dated December 14, 2007 (Exhibit A), please issue a refund in the amount of $120.00 which was paid by Deposit Account No. 23-0785 on January 29, 2008 (Exhibit B), for filing of a Response to Office Action dated September 24, 2007 which was timely filed on December 26, 2007 (Exhibit C). Should you have any further questions, please don't hesitate to contact the undersigned.

Respectfully submitted,

Date: February 19, 2008

Mark V. Polyakov, Reg. No. 54,377
Wood, Phillips, Katz, Clark & Mortimer
500 West Madison Street, Suite 3800
Chicago, Illinois 60661-4592
Telephone: (312) 876-1800
Facsimile: (312) 876-2020

Closing of the United States Patent and Trademark Office on Monday, December 24, 2007

The United States Patent and Trademark Office (USPTO) will be closed on Monday, December 24, 2007. Since Tuesday, December 25, 2007 is a Federal holiday, the USPTO will consider both Monday, December 24, 2007 and Tuesday, December 25, 2007, to be a "Federal holiday within the District of Columbia" under 35 U.S.C. § 21(b) and 37 C.F.R. §§ 1.6, 1.7, 1.9, 2.2(d), 2.195 and 2.196. Any action or fee due on these days (or the preceding Saturday (December 22, 2007) or Sunday (December 23, 2007)) will be considered as timely for the purposes of, e.g., 15 U.S.C. §§ 1051(b), 1058, 1059, 1062(b), 1063, 1064, 1126(d), or 35 U.S.C. §§ 119, 120, 133 and 151, if the action is taken, or the fee paid, on the next succeeding business day on which the USPTO is open, that is, Wednesday, December 26, 2007. 37 C.F.R. §§ 1.7(a) and 2.196.

37 C.F.R. §§ 1.6(a)(2), 2.195(a)(4) and 2.198 provide that correspondence deposited in the Express Mail Service of the United States Postal Service (USPS) in accordance with 37 C.F.R. §§ 1.10 or 2.198 will be considered filed on the date of deposit (as shown by the "date-in" on the Express Mail mailing label) with the USPS. Thus, any paper or fee properly deposited in the Express Mail Service of the USPS on Monday, December 24, 2007, or Tuesday, December 25, 2007, in accordance with 37 C.F.R. §§ 1.10 or 2.198 will be considered filed on its respective date of deposit in the Express Mail Service of the USPS (as shown by a "date-in" of December 24, 2007, or December 25, 2007, on the Express Mail mailing label, respectively).

37 C.F.R. § 1.6(a)(4) and 37 C.F.R. § 2.195(a)(2) provide that patent and trademark-related correspondence transmitted electronically to the USPTO will be considered filed in the USPTO on the date the USPTO received the electronic transmission. Thus, any patent and/or trademark-related correspondence transmitted electronically to the USPTO on Monday, December 24, 2007, or Tuesday, December 25, 2007, will be considered filed in the USPTO on the date the USPTO received the complete electronic transmission. Correspondence successfully received by the USPTO through the patent Electronic Filing System (EFS-Web) will receive the date as indicated on the Acknowledgment Receipt.

12/14/07
DATE

JON W. DUDAS
Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office

Exhibit A

$510.00 - 587.00

United States Patent and Trademark Office

Deposit Account Statement

Requested Statement Month:	January 2008
Deposit Account Number:	230785
Name:	WOOD, PHILLIPS, KATZ, CLARK & MORTIMER
Attention:	DONNA GVOZDEN
Street Address 1:	500 WEST MADISON STREET
Street Address 2:	SUITE 3800
City:	CHICAGO
State:	IL
Zip:	60661
Country:	UNITED STATES

DATE	SEQ	POSTING REF TXT	ATTORNEY DOCKET NBR	FEE CODE	AMT	BAL
01/02	7	PCT/US07/26455	10468P00010PC	1602	$955.00	$1,104.00
01/03	9354	E-REPLENISHMENT		9203	-$8,977.00	$10,081.00
01/04	555	0181080778	COR01896P00101FOREIGN	8014	$425.00	$9,656.00
01/04	19	29251231	10397D0004US	9204	-$10.00	$9,666.00
01/07	14	PCT/US07/21702		9204	-$20.00	$9,686.00
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01/08	2	10960659	01488P00100US 170US	1201	$210.00	$9,536.00
01/08	254	PCT/US08/00199	SEA00820P01610PC	1602	$1,627.00	$7,909.00
01/09	1	11281638	OXF6016P0130US	1202	$250.00	$7,659.00
01/09	2	11281638	OXF6016P0130US	1201	$420.00	$7,239.00
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01/11	2	11275443	924023-102295 10404P00043US	1201	$210.00	$6,837.00
01/14	11582	0203110454	1228 10078P00040MX	8014	$25.00 ✓	$6,812.00
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01/16	9797	60898533	VAL06131P00991CL	8007	$20.00 ✓	$6,772.00
01/16	9809	60898477	VAL06131P00881CL	8007	$20.00 ✓	$6,752.00
01/16	9819	60898457	VAL06131P00881CL	8007	$20.00 ✓	$6,732.00
01/16	9850	60898633	VAL06131P00881CL	8007	$20.00 ✓	$6,712.00
01/16	9861	60898530	VAL06131P00881CL	8007	$20.00 ✓	$6,692.00
01/16	9877	60898534	VAL06131P00881CL	8007	$20.00 ✓	$6,672.00
01/16	9890	60898470	VAL06131P01001CL	8007	$20.00 ✓	$6,652.00
01/16	9905	60936395	VAL06131P01001CL	8007	$20.00 ✓	$6,632.00

Put Note Sheets

$100 600

Please charge Exhibit B

	10236	60958321	VAL06131P01001CL	8007		$20.00	$6,612.00
01/16	10251	60898532	VAL06131P00961CL	8007		$20.00	$6,592.00
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01/22	4	PCT/US07/26455	10468P00010PC	1704		$1,312.00	$6,030.00
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01/23	7	11024183	10003P00010US	2401		$5.00	$5,567.00
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01/28	10698	11803784	1229 10183P00050US	8007		$20.00	$2,827.00
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01/28	222	10962348	00682P00[illegible]S P00311US	1401		$10.00	$2,792.00
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01/29	2	10815320	PIE1514P0182US	1251		$120.00	$2,712.00 *
01/30	8438	11700484	1231 00917P00470US	8007		$80.00	$2,632.00
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01/30	11421	0204210416	COR01896P00101 FOREIGN	8014		$375.00	$2,237.00

Exhibit * B pg. 2

put note on entry

START BALANCE	SUM OF CHARGES	SUM OF REPLENISH	END BALANCE
$2,059.00	$9,984.00	$10,162.00	$2,237.00

PTO/SB/21 (10-07)
Approved for use through 10/31/2007. OMB 0651-0031
U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE
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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

Total Number of Pages in This Submission: 10

Application Number	10/816,320
Filing Date	April 1, 2004
First Named Inventor	Hans Binz et al.
Art Unit	1645
Examiner Name	Devi, Sarvamangala J N
Attorney Docket Number	PIE1514P0182US

ENCLOSURES (Check all that apply)

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☑ Amendment/Reply
  - ☐ After Final
  - ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Reply to Missing Parts/ Incomplete Application
  - ☐ Reply to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) _____
  - ☐ Landscape Table on CD
- ☐ After Allowance Communication to TC
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
- ☐ Proprietary Information
- ☐ Status Letter
- ☑ Other Enclosure(s) (please identify below):
  Return receipt postcard

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm Name	Wood Phillips Katz Clark & Mortimer		
Signature			
Printed name	Mark Poiyakov		
Date	December 26, 2007	Reg. No.	54,377

CERTIFICATE OF TRANSMISSION/MAILING

I hereby certify that this correspondence is being facsimile transmitted to the USPTO or deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date shown below:

Signature			
Typed or printed name	Alicia Diaz	Date	December 26, 2007

This collection of information is required by 37 CFR 1.5. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11 and1.14. This collection is estimated to 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: **Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.

Exhibit C

PIE01514P00182US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	) CARRIER PROTEIN HAVING AN ADJUVANT EFFECT, IMMUNOGENIC COMPLEX CONTAINING IT, PROCESS FOR THEIR PREPARATION, NUCLEOTIDE SEQUENCE AND VACCINE
H. Binz et al.	)
Serial No. 10/815,320	) Group Art Unit: 1645
Filed: 04/01/2004	) Examiner: S. Devi

RESPONSE TO OFFICE ACTION

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the Office Action dated September 24, 2007 in connection with the above-identified patent application, please consider the following amendments and remarks. If any additional fees are required as a result of the filing of this paper, the Commissioner is hereby authorized to charge to Deposition Account No. 23-0785 any such fees.

AMENDMENTS TO THE SPECIFICATION

Amendments to the Specification begin on page 2 of this paper.

AMENDMENTS TO THE CLAIMS

Amendments to the claims are reflected in the listing of claims which begins on page 6 of this paper.

REMARKS

Remarks begin on page 9 of this paper.

In the Specification:

Please insert the following paragraph at the top of the first page and immediately before "CROSS-REFERENCE TO RELATED APPLICATIONS":

TITLE OF THE INVENTION

Carrier Protein Having an Adjuvant Effect

Please replace the paragraph immediately after "CROSS-REFERENCE TO RELATED APPLICATIONS" with the following:

This application is a division of Application Serial No. 09/679,750, filed 10/05/2000, now US Patent No. 6,780,420, which is a continuation of application Serial No. 08/836,500, filed 08/11/97, now US Patent No. 6,197,929, which is a national stage 371 application of the international application PCT/FR95/01463, which claims foreign priority to application 94,13306 filed 07/11/1994 in France.

Please insert the following heading immediately after the paragraph dealing with "CROSS-REFERENCE TO RELATED APPLICATIONS":

STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH AND DEVELOPMENT

Not Applicable

Please insert the following heading immediately after the paragraph dealing with "STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH AND DEVELOPMENT":

THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT

Not Applicable

Please insert the following heading immediately after the paragraph dealing with "THE NAMES OF THE PARTIES TO A JOINT RESEARCH AGREEMENT":

REFERENCE TO A "SEQUENCE LISTING"

The application contains "Sequence Listing" in the computer readable form. The computer readable form is identical with that filed in Application Serial No. 08/836,500, filed 08/11/97, now US Patent No. 6,197,929.

Please insert the following heading immediately after the paragraph dealing with "Reference to a "Sequence Listing"":

FIELD OF THE INVENTION

Please insert the following heading immediately after line 9 of page 1 and immediately before line 10 (i.e. the sentence that starts, "The development of vaccines...") of page 1 in the originally submitted translation:

BACKGROUND ART

Please insert the following heading immediately after line 32 of page 1 and immediately before line 33 (i.e. the sentence that starts, "The Applicant has demonstrated...") of page 1 in the originally submitted translation:

SHORT SUMMARY OF THE INVENTION

Please insert the following heading immediately after line 11 of page 6 and immediately before line 12 (i.e. the sentence that starts, "In these examples...") of page 6 in the originally submitted translation:

BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWINGS

Please insert the following heading immediately after line 24 of page 6 and immediately before line 25 (i.e. the sentence that starts, "Example 1: Isolation...") of page 6 in the originally submitted translation:

DETAILED DESCRIPTION OF THE INVENTION

Please replace the paragraph that starts on line 4 of page 7 with the following:

The pellets obtained after the second precipitation are resuspended in a 1% solution of ~~zwittergent~~ Zwittergent® 3-14.

Please replace the paragraph that starts on line 13, page 7 with the following:

The proteins of the MP fraction are dialysed against a 20 mM Tris/HCl, pH 8.0; 0.1% ~~zwittergent~~ Zwittergent ® 3-14 buffer. The dialysate is loaded onto a column

containing a support of the strong anion exchanger type (column of ø = 50 mm x H = 250 mm, Biorad® Macroprep High Q gel) which is equilibrated in the above-described buffer. The P40 protein is eluted at an NaCl concentration of 50 mM in the equilibration buffer.

Please replace the paragraph that starts on line 21, page 7 with the following:

The fractions containing the P40 are pooled and dialysed against a 20 mM citrate, pH 3.0; 0.1% ~~zwittergent~~ Zwittergent ® 3-14 buffer. The dialysate is loaded onto a column containing a support of the strong cation exchanger type (diamensions of the column: ø = 25 mm x H = 160 mm, Biorad® Macroprep High S gel) which is equilibrated in the 20 mM citrate, pH 3.0; 0.1% ~~zwittergent~~ Zwittergent ® 3-14 buffer. The P40 protein is eluted at an NaCl concentration of 0.7 M. The fractions containing the P40 are pooled and concentrated by ultrafiltration using a Minitan® Millipore tangential flow filtration system employing membrane discs having a cutoff threshold of 10 kDa.

Please replace the paragraph that starts on line 9, page 10 with the following:

Gene amplification

Lysis buffer:	25 mM Taps, pH 9.3 2 mM $MgCl_2$
Amplification buffer:	25 mM Taps, pH 9.3 2 mM $MgCl_2$ 0.1% Tween® 20 200 mM dNTP.

Please replace the paragraph that starts on line 16, page 10 with the following:

TST (20x) :	Tris base	0.5 M
	HCl	0.3 M
	NaCl	4 M
	Tween® 20	1%
	EDTA	20 mM

Washing buffer:	Tris HCl	50 mM	pH 8.5
	$MgCl_2$	5 mM	
Denaturation solution:	Gua – HCl	7.8 M	
	Tris-HCl	28 mM	pH 8.5
Renaturation solution:	Gua-HCl	0.5 M	
	Tris-HCl	25 mM	pH 8.5
	NaCl	150 mM	
	Tween® 20	0.05%	

Please replace the paragraph that starts on line 24, page 11 with the following:

These reactions are carried out in 100 µl of amplification buffer using 5 pmol of each primer and 1 unit of Taq polymerase enzyme (Perkin Elmer Cetus). Each cycle comprises one denaturation step of 30 seconds at 95°C, followed by hybridization of the primer to the DNA and an extension of one minute at 72°C. 30 cycles are performed in this way using a Perkin Elmer Cetus "Gen Amp PCR"® 9000 thermocycler.

Please replace the paragraph that starts on line 2, page 12 with the following:

The fragments which have thus been cloned are sequenced on an Applied Biosystems 373 automated DNA Sequencer. The sequencing reactions are carried out using the "Dye Terminator"® kit in accordance with the supplier's (Applied Biosystems) recommendations either on double-stranded DNA obtained after gene amplification or derived from a maxiprep, or on single-stranded DNA drived from denatured PCR fragments (Hultman, T. et al., *1989*, Nucleid Acids Rev. 17: 4937-4946).

In the Claims:

1. (Cancelled)

2. (Cancelled)

3. (Cancelled)

4. (Cancelled)

5. (Cancelled)

6. (Cancelled)

7. (Withdrawn) DNA sequence encoding an adjuvant comprising at least the fragment of the P40 protein Klebsiella pneumoniae, said fragment having the amino acid sequence of SEQ ID No: 8.

8. (Cancelled)

9. (Cancelled)

10. (Cancelled)

11. (Cancelled)

12. (Cancelled)

13. (Cancelled)

14. (Cancelled)

15. (Cancelled)

16. (Withdrawn) A pharmaceutical composition comprising said DNA sequence of claim 7, and a pharmaceutically acceptable carrier.

17. (Withdrawn) A vaccine for intramuscular or intradermal administration comprising said DNA sequence of claim 7.

18. (Cancelled)

19. (Currently Amended) A ~~Process~~ process for increasing the immunogenicity of an antigen or a hapten, characterized in that the said process comprises the step of attaching the antigen or the hapten ~~is attached~~ to an adjuvant to form an immunogenic complex, said adjuvant comprising ~~the~~ a fragment having the sequence ~~127 to 179~~ (SEQ ID No. ~~8~~) of the P40 protein of *Klebsiella* ~~K. pneumoniae~~ *pneumoniae* having the sequence SEQ ID No. 2.

20. (Currently Amended) The ~~Process~~ process according to claim 19, characterized in that said adjuvant is ~~the~~ a fragment having the sequence ~~108 to 179~~ (SEQ ID No. ~~6~~) of the P40 protein of ~~K. pneumoniae having the sequence ID No. 2~~ *Klebsiella pneumoniae*.

21. (Currently Amended) The ~~Process~~ process according to claim 19, characterized in that said adjuvant is ~~the~~ a fragment having the sequence ~~1 to 179~~ (SEQ ID No. ~~4~~) of the P40 protein of ~~K. pneumoniae having the sequence ID No. 2~~ *Klebsiella pneumoniae*.

22. (Currently Amended) The ~~Process~~ process according to claim 19, characterized in that said adjuvant is the P40 protein of ~~K. pneumoniae~~ *Klebsiella pneumoniae* having the sequence ID No. 2.

23. (Cancelled)

24. (Currently Amended) The ~~Process~~ process according to claim 19, characterized in that said antigen or ~~a~~ the hapten consists of a an immunogenic fragment of the G protein of the respiratory syncytial virus (RSV).

25. (Currently Amended) The ~~Process~~ process according to claim 19, characterized in that said antigen or the a hapten is attached to the adjuvant by a covalent bond.

26. (Currently Amended) The ~~Process~~ process according to claim 19, characterized in that said antigen or the hapten is attached to the adjuvant by chemical coupling.

27. (Currently Amended) The ~~Process~~ process according to claim 19, characterized in that said antigen or the hapten is fused to the adjuvant by genetic manipulation.

28. (Currently Amended) The ~~Process~~ process according to claim 19, characterized in that said antigen or the ~~a~~ hapten which is attached to the adjuvant, is fused to a protein which is a receptor for a serum protein.

29. (Currently Amended) The ~~Process~~ process according to claim 19, characterized in that said antigen or the ~~a~~ hapten which is attached to the adjuvant, is fused to a protein which is a receptor for the human serum albumin.

REMARKS

This is in response to the Office Action mailed on September 24, 2007. Claims 19-29 are currently pending and are at issue.

According to the Examiner's suggestion, Applicants have amended the specification to introduce Section Headings and to correct other informalities.

Claim 24 has been further amended to recite "immunogenic" fragment of the G protein. Support can be found, for example, at page 5, lines 12-16.

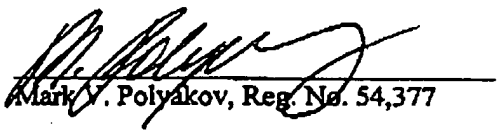
§112, Second Paragraph

The Office Action rejected claims 19-29 under 35 U.S.C. §112, second paragraph as allegedly being indefinite. Applicants have amended claims 19-22 and 24-29 and have canceled claim 23. Applicants believe that the amendments address and overcome the rejection.

Conclusion

Applicants respectfully submit that all rejections have been overcome by amendments and/or arguments. Favorable consideration and allowance of claims is respectfully requested. If the Examiner has any questions or concerns, she is welcome to telephone the undersigned attorney.

Respectfully submitted,



Mark V. Polyakov, Reg. No. 54,377

Wood, Phillips, Katz, Clark & Mortimer
500 West Madison Street, Suite 3800
Chicago, Illinois 60661-4592
Telephone: (312) 876-1800
Facsimile: (312) 876-2020
Date: December 26, 2007

CERTIFICATE OF MAILING

I hereby certify that this paper is being deposited with the United States Postal Service with sufficient postage at First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450 on **December 26, 2007.**

Alicia Diaz

Intellectual Property Law
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Suite 3800
Chicago, Illinois 60661-2562
T (312) 876.1800
F (312) 876.2020
www.woodphillips.com

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FACSIMILE TRANSMISSION

Date: February 19, 2008

To: REFUND DEPARTMENT
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